REMARKS

The remarks herein are responsive to the Final Office Action dated 28 December 2009. Claims 8-25, 29-36, 42, 43, 45, and 46 remain pending. No new claims have been added, canceled, or amended. Applicant thanks the Examiner for his time and comments during the Examiner interview.

All the claims now stand rejected under 35 U.S.C. § 103 as being unpatentable over Steinemann (U.S. Pat. No. 5,456,723) in combination with at least one or more of Pilliar (U.S. Pat. No. 3,855,638), Rowe (U.S. Pat. No. 4,542,539), and Shimamune (U.S. Pat. No. 5,034,186). Pilliar and Rowe generally teach the creation of larger pores on prosthetics and implants. Shimamune teaches a general sintering procedure with relatively little description of the resulting surface. Steinemann generally teaches a process involving an acid etch to produce small surface features on a metallic implant, supported by experimental results indicating that smaller pores are superior to larger pores. Steinemann is cited in the Office Action as disclosing "a surface micro-structure," and the other references are cited as disclosing "an open-pored structure" or "an open-pored implant surface."

There Was No Motivation to Combine the References

One of skill in the art at the time of the invention would not be motivated to combine Steinemann with these references. Steinemann promotes a small roughening while the other references, such as Pilliar, promote large open-pores. As each idea promotes a different scale of roughening, the limited independent success of each idea was previously considered contradictory. For example, Steinemann recites:

> "Actual tests performed on implants according to the invention showed that a porous contact surface on a metallic implant is **able to meet the conditions required** for making the mating bone intergrow with the implant along the contact surface and speedily form a strong and durable bond, **provided that** the contact surface displays a micro-roughness with pits of the order of magnitude of **2µm or less**." Steinemann at (3:17-24) (emphasis added)

Steinemann describes these results as "**stand[ing] in perfect contrast to opinions expressed so far in literature [such as those requiring] a contact surface roughness of more then 20 µm**." Steinemann at (6:30-31).

Pilliar is an example of the literature Steinemann contrasts. For example, Pilliar states that "**it is essential** that the interstitial pore size **exceed about 50 microns**." Pilliar at (3:51-54) (emphasis added). Similarly, Rowe recites that "[a] pore size range between 100 and 500 micrometers is such as to encourage bone ingrowth." Rowe at (5:38-40).

Thus, the references teach two distinct pore sizes: small pores "2μm or less," and large pores such as "exceed[ing] about 50 microns." As stated by Dr. Frauchiger[1], "[f]or almost 20 years [these] two contradictory ideas developed independently." Frauchiger Declaration at ¶9. Dr. Frauchinger further noted that, "[a]bsent a deeper understanding of each method's underlying mechanisms, one of ordinary skill had no motivation to combine the two." Frauchiger Declaration at ¶9. Steinemann indicates no such understanding, as its results stand "in perfect contrast" to the references that came before it. Clearly, Steinemann viewed these results as contradictory and not potentially cumulative.

As realized by the Applicants, the open pores and submicron roughness provide completely different mechanisms for binding bone with the implant surface. Large open pores such as those in Pilliar allow bone tissue to grow into and under the implant surface through the pores, creating a stronger interlocking mechanical connection between the bone and the implant. Dr. Frauchiger notes that the "non-open… sandblasted pits of Steinemann would not provide the same functionality." Frauchiger Declaration at ¶11. However, the smaller surface features of Steinemann allow bone cells to grow onto and adhere to the surface on a microscopic scale – a distinct mechanism of adhesion from that of the open pores.

As noted by Dr. Frauchiger, both of these large and small pores were known at the time of the invention, but their combination was not considered and in fact was taught away from, as discussed further below. Steinemann specifically addressed the large-pore techniques of Pilliar, but did not consider the combination now proposed in the Office Action. Instead Steinemann distinguished these techniques, indicating that those of skill in the art at the time lacked motivation to combine the techniques. *See, e.g.*, Frauchiger Declaration at ¶¶9, 14. Thus, Applicants submit that the combination of Steinemann with references such as Pilliar is improper for lack of motivation.

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[1] Dr. Frauchinger submitted a declaration that was filed along with the Amendment filed on 9 April 2009.

Steinemann Teaches Away From the Other Reference's Pore Sizes

The combination of Steinemann with references such as Pilliar is also improper because they teach away from each other. References such as Pilliar and Rowe, which prescribe large open-pores, clearly teach away from the claimed micro-structures allegedly disclosed in Steinemann. Similarly, Steinemann teaches away from these large open-pores. As discussed above, the references **teach mutually exclusive ranges for pore size**, and further emphasize the importance of these ranges. Further, as discussed above, Steinemann describes its experimental results indicating the effectiveness of small pores as being **"in perfect contrast"** with the large-pore literature. **References "in perfect contrast" usually teach away from each other.**

Steinemann Does Not Teach Providing a Microroughness Over a Porous Surface

Previous Office Actions have asserted or implied that Steinemann teaches providing a microroughness on a porous surface. For example, Claim 6 recites: "a porous metallic biocompatible surface… wherein the [surface] is provided with micro-roughness and a fine pitting is superimposed on the micro-roughness." A first interpretation of this may indicate three layers of features: (1) a porous surface, with (2) a micro-roughness on the porous surface, and (3) a fine pitting on the micro-roughness. A second interpretation may indicate two layers of features: a porous surface defined by (1) a micro-roughness with (2) a fine pitting thereon. However, as outlined in Applicant's previous Amendment, Applicant submits that a third interpretation is correct: there is only one feature.

As explained in the previous Amendment beginning at page 7, Steinemann uses the terms "pits," "pores," and "microroughness" interchangeably to describe both sandblasted pits and acid pits. Further, the acid pits are the only features that have any effect, as described by Steinemann. Referencing the experimental results, Steinemann states:

> "The improvements were unquestionably related to the **main feature of the invention**, namely, that the contact surface was provided with a micro-roughness having an R_t greater than 10 μm and an RS less than 10 μm. This micro-roughness was produced by means of an acid treatment using a reducing acid. **This operation alone produced the results desired** by effectively pitting the surface of the metallic surface to be implanted. Sandblasting may be used, however, as a step preceding the reducing acid treatment." Steinemann at 3:38-46 (emphasis added)

Thus, Steinemann teaches that the acid pits alone are sufficient to produce the desired results.

However, the paragraph continues, indicating that the sandblasting has no lasting effect. It states that the "R_t [is] larger than 10 μm as impressed by the sandblasted grain;" but earlier in that paragraph (quoted above) Steinemann states that the same result (R_t greater than 10 μm) is achieved by the acid alone. Thus, it appears that the acid etch in Steinemann destroys any features produced by the sandblasting, such that the sandblasting has no lasting effect. The primacy of the acid etch and the resulting "pits of the order of magnitude of 2 μm or less" in Steinemann are highlighted when Steinemann contrasts its experimental success with the larger pores taught by the prior art at (6:20-33): "[c]ompletely new, unexpected and surprising were… the results obtained when providing… reducing acid."

Thus, Steinemann teaches that the acid pits are sufficient to produce the desired results, and does not indicate any effect from the sandblasted pits. Further, even if the sandblasted pits do have an effect, they are merely pits and not open pores as claimed.

Pilliar and Steinemann Teach Away from Vacuum Plasma Spraying

As described by Pilliar:

> "[A] result of plasma or flame spraying is that a very hot molten mass impinges on a relatively cold substrate surface causing the setting up of considerable interfacial thermal stresses which result in an inherent weakness which manifests itself in the interfacial shearing action observed in tests." Pilliar at (2:14-19)

Thus, Pilliar teaches that plasma spraying causes an inherent weakness and interfacial tearing at the surface. The stated goal of Pilliar is to "overcome[] the weakness problems associated with the prior art devices, as discussed above." Pilliar at (2:40-43). Thus, Pilliar clearly teaches away from plasma spraying.

Steinemann's position on plasma spraying is consistent with Pilliar. For example, Steinemann confirms Pilliar's conclusion that "the mechanically brittle plasma layer has a tendency to break or peel off." Steinemann at (2:4-5). Steinemann's experimental results confirmed this, as "[t]he anchoring effect or removing torque [was] not less than 30% larger than the removing torque obtained by the use of the plasma coat." Steinemann at (6:23-27). Thus, it should not be surprising that "[a]nother object of the invention [in Steinemann] relates to an implant… in which the improved surface texture is formed directly in the metal mass… rather than on a brittle plasma

coating." Steinemann at (2:56-61). Thus, Steinemann also clearly teaches away from plasma spraying.

Rejections of Claims Under 35 U.S.C. § 103

The pending claims stand rejected under 35 U.S.C. § 103 as being unpatentable over Steinemann in combination with at least one of Pilliar, Rowe, and Shimamune. As discussed above, Applicant respectfully submits that the combination of Steinemann with the other references to show a surface with open-pores and a surface micro-structure, among other limitations in the claims, is inappropriate. Further, the independent claims 8 and 33 both recite a vacuum plasma spraying method. However, as discussed above, at least Steinemann and Pilliar teach away from the use of a vacuum plasma spraying method.

For at least the reasons described above and in previous communications, Applicants submit that Claims 8 and 33 are allowable over Steinemann in view of the other cited references. Claims 9-25, 29-32, 34-36, 42, 43, 45, and 46 depend from independent Claims 8 and 33 and are therefore likewise allowable over the cited references, not only because they depend from an allowable base claim, but also because each of these claims recites a unique combination of features, not taught or suggested by the cited art.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

Co-Pending Applications of Assignee

Applicant wishes to draw the Examiner's attention to the following co-pending applications of the present application's assignee.

Docket No.	Serial No.	Title	Filed
MEISS71.033APC	11/722,697	A METHOD OF SURFACE FINISHING A BONE IMPLANT	12/22/2005
MEISS71.039APC	12/092,545	OPEN-PORE BIOCOMPATIBLE SURFACE LAYER FOR AN IMPLANT, METHODS OF PRODUCTION AND USE	5/2/2008

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated: March 29, 2010

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